DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration

May 1, 2002

Dear Mammography Quality Advocate:

Under the Mammography Quality Standards Act (MQSA) of 1992, we are required to prepare an annual report of adverse actions taken against mammography facilities. The purpose of the report is to assist health professionals and consumers to evaluate the performance of their mammography facilities. The document (attached) is titled **"Mammography Facility Adverse Event Report - 2001."** We encourage you to make this information available to your constituents, especially physicians and the general public.

The report includes the following:

- background information, and
- a list of facilities against which adverse actions were taken in 2001.

You will find this report, along with other MQSA related documents, on our mammography web site, www.fda.gov/cdrh/mammography. Select "Publications," then select "Reports" from the list of choices.

If you have any questions about this report, please send them to Patti Hoage at pah@cdrh.fda.gov.

Sincerely yours,

CAPT John L. McCrohan, USPHS
Director
Division of Mammography Quality
and Radiation Programs
Office of Health and Industry Programs
Center for Devices and Radiological Health

Attachment

MAMMOGRAPHY FACILITY ADVERSE EVENT REPORT - 2001

BACKGROUND

Congress enacted the Mammography Quality Standards Act (MQSA) in 1992, marking the first time mammography facilities were required by the federal government to meet strict quality standards. The intent of MQSA is to assure the quality of mammography nationwide. Mammography can detect breast cancer in its earliest, most treatable stages. Studies show that widespread use of mammography can reduce deaths from breast cancer by one-third. In the fall of 1998, Congress re-authorized MQSA, extending the program through fiscal year 2002.

Congress charged the Food and Drug Administration (FDA) with implementing and enforcing MQSA. With the help of the National Mammography Quality Assurance Advisory Committee, we developed interim regulations, initiated an inspection program, and issued comprehensive final regulations that became effective on April 28, 1999. The final regulations toughen the 1994 interim standards for personnel, equipment, quality assurance and quality control, and reporting of exam results as well as requirements for accreditation bodies.

Of particular importance to women is the MQSA regulation that requires mammography facilities to give patients an easy-to-read report of the results of their mammogram. Prior to MQSA, mammography facilities were not required to communicate results directly to patients and, instead, sent results only to the referring physician. Referring physicians will continue to receive the results. Self-referred patients with no designated health-care provider will receive both the simplified report and the one doctors normally receive.

MQSA also clarifies a facility's responsibility to retain and transfer mammograms to a patient's physician or to the patient directly, regardless of whether the transfer is permanent or temporary. This is important because it aids diagnosis by allowing doctors to compare old mammograms with new ones.

To help patients understand these and other changes that affect them, we developed and widely distributed a brochure titled "*Mammography Today – Questions and Answers for Patients on Being Informed Consumers.*" You can find the brochure on our web site at www.fda.gov/cdrh/mammography, select "Consumers", and then select the brochure.

We have been conducting inspections under the final regulations since July 1999. A study of current inspection findings shows a decrease in serious and moderate non-compliances.

As of April 15, 2002, there were 9,441 MQSA certified mammography facilities operating in the United States. Of these 9,211 were fully certified. The remaining facilities are in the process of becoming accredited and are provisionally certified.

In order to gather data for this report, we consulted with and received reports from the following entities:

- The Inspector General, Health and Human Services (HHS), Center for Medicare and Medicaid Services (formerly the Health Care Financing Administration) for data about fraud abuse kickbacks and false billing under Medicare and Medicaid.

- The five MQSA accreditation bodies for reports of revocation of accreditation and cease and desist orders.

- FDA's Inspection and Compliance Branch, Division of Mammography Quality and Radiation Programs, OHIP, CDRH, for actions taken against mammography facilities.

- FDA's Office of Criminal Investigations for criminal prosecution against individuals associated with mammography facilities.

- All States and U.S. territories for actions they have taken against mammography facilities.

MEDICARE/MEDICAID ACTIONS

The HHS Inspector General lists no conviction data under **Medicare** for cases related to mammography facilities in 2001. This includes prosecutions or convictions of mammography facilities under federal or State laws relating to fraud and abuse, false billings or kickbacks.

The HHS Inspector General also reports that no **Medicaid** actions were taken against mammography facilities in 2001.

ACCREDITATION BODY ACTIONS

Each year, we ask all of the accreditation bodies to report if they revoked the accreditation of any facilities accredited by them. Revocation means withdrawal of a facility's accreditation prior to the expiration date for reasons other than voluntary withdrawal by the facility. Currently, there are five FDA-approved accreditation bodies – the American College of Radiology (ACR) and the States of Arkansas, California, Iowa and Texas.

The American College of Radiology and the States of Arkansas, Iowa and Texas reported no revocations of any facilities during 2001.

At this time, the State of California does not revoke, but rather issues cease and desist orders under State regulations. California issued one such order. See the California section below.

FDA ACTIONS

MQSA Actions

Med-Scan Flint
G3247 Beecher Road
Flint, MI 48532

FDA facility ID:	172676
Adverse action:	FDA issued a Warning Letter on March 7, 2000.
Reason for action:	Phantom image failure and failed targeted film check with possible risk to human health.
Corrective action:	Facility voluntarily notified patients and physicians about possible compromise of mammography quality. This notification was completed on July 7, 2001. Facility voluntarily closed.
Status of facility:	Not performing mammography.

Women's Mobile Diagnostic, Ltd.
360 Gardner Street
Philadelphia, PA 19116

FDA facility ID:	219956
Adverse action:	FDA required the facility to notify patients and physicians of possible compromise of mammography quality. This notification was completed on December 20, 2001.

Reason for action: Facility was put under a Directed Plan of Correction due to continuing failures to perform equipment quality tests properly and to have an effective quality assurance program for mammography. The facility failed to comply with this plan. FDA requested the facility's accreditation body to conduct an onsite visit and they found problems with clinical image quality.

Corrective action: Facility voluntarily withdrew their accreditation and closed.

Status of facility: Not performing mammography.

FDA's Office of Criminal Investigations

Dale Medical Center
100 Hospital Avenue
Ozark, AL 36360

FDA facility ID: 108795

Adverse Action: Criminal prosecution of an individual, Melanie Dee Smith, under Title 18 USC, Section 1001.

Reason for action: Ms. Smith, a radiologic technologist at Dale Medical Center, was formally indicted by the Grand Jury for falsifying and destroying documents and giving false statements to a government official.

Corrective action: Ms. Smith was charged with obstruction of justice and making false statements and was arrested on August 22, 2001. The Assistant U.S. Attorney prosecuting this case advised that Ms. Smith entered into a Pre-Trial Diversion agreement on November 20, 2001. The Pre-Trial Diversion agreement requires that the defendant not be involved with mammography during the eighteen month period of the agreement.

Status of facility: Performing mammography.

Harris Hospital
1205 Mclain Street
Newport, AR 72112

FDA facility ID: 203323

Adverse action: FDA issued a Warning Letter on September 19, 2001. The letter included an agreement for removal of an employee from management oversight of Harris' mammography program for no less than five years. The Assistant U.S. Attorney in Little Rock, Arkansas negotiated a proposed settlement with Harris Hospital for $65,000 under the False Claims Act.

Reason for action: Falsification of records, inadequate quality control tests, and equipment performance problems.

Corrective action: The facility corrected all of the problems relating to their equipment and quality assurance program. The employee most responsible for the falsification of records is no longer employed at Harris Hospital.

Status of facility: Performing mammography.

STATE'S ACTIONS

MQSA does not preclude a State or U.S. territory from having stricter mammography requirements. In States that have additional requirements, facilities are required to comply with both State and MQSA regulations to operate lawfully.

Adverse actions reported here were taken by States. We included only those cases that compare to those that would be the subject of adverse actions under MQSA. A total of three States reported adverse actions for calendar year 2001.

California

Pacific Coast Medical Services
1544 East Katella Avenue
Anaheim, CA 92805

FDA facility ID: 191098

Adverse action:	State issued a Cease and Desist Order on September 27, 2001, requiring the facility to stop performing mammography and required the facility to notify patients and physicians of possible compromise of mammography quality.
Reason for action:	Facility failed a directed clinical image review required by the State of California accreditation body. The review was ordered because the State received a complaint about the facility's film quality.
Corrective action:	Personnel training completed October 2001. Facility notified patients and physicians as requested by the State and completed the notification procedure on December 10, 2001.
Status of facility:	Performing mammography.

St. Francis Medical Center
3630 East Imperial Highway
Lynwood, CA 90262

FDA facility ID:	138560
Adverse action:	State and the facility entered into a Voluntary Agreement on June 1, 2001. The agreement outlines specific actions that the State will monitor in order to improve the facility's clinical images.
Reason for action:	During its regular accreditation renewal process the facility failed a clinical image review.
Corrective action:	State ordered a peer film review of 289 exams performed between November 1, 2000 and April 1, 2001. The review was conducted by an interpreting physician from a local major medical center and was completed on December 5, 2001. The review identified only minor problems. The State determined that the facility had met the agreement and fully accredited the facility.
Status of facility:	Performing mammography.

New York

Steven J. Bier, M.D.
2488 Grand Concourse
Bronx, NY 10458

FDA facility ID: 140780

and

New York Diagnostic
Medical Services
102 Park Avenue
Yonkers, NY

FDA facility ID: 216861

Adverse action:	Combined efforts between FDA and New York State resulted in the facilities notifying patients and physicians of possible compromise of mammography quality. The notification (initiated in late 2000) was completed April 11, 2001.
Reason for action:	Facilities failed New York State's clinical image review. The review was conducted after an audit of the facilities' activities as a participant in the Centers for Disease Control and Prevention's National Breast and Cervical Cancer Early Detection Program revealed abnormalities.
Corrective action:	Facilities voluntarily withdrew their certification.
Status of facility:	Not performing mammography.

Texas

Fredericksburg Imaging Center
Hill Country Memorial Hospital
1020 Kerrville Highway
P.O. Box 835
Fredericksburg, TX 78624

FDA facility ID:	116558
Adverse action:	Facility paid $5,000 in punitive fines, and performed mammography public service activities.
Reason for action:	Facility failed to perform phantom image quality evaluations and processor performance evaluations. Facility failed to take corrective action when the phantom image quality evaluation and processor performance evaluation indicated they were operating outside the established parameters.
Corrective action:	Facility re-established all quality control testing at the required intervals. On March 4, 2002, FDA conducted an unannounced inspection. The facility was in compliance for all items and met the annual MQSA inspection requirements.
Status of facility:	Performing mammography.

How to Find an FDA-Certified Facility

To operate legally, a mammography facility must have and prominently display a Food and Drug Administration (FDA) certificate or a similar certificate from a State certifying body. This certificate shows that the mammography facility is certified as meeting baseline quality standards for equipment, personnel, and practices under the Mammography Quality Standards Act (MQSA).

Internet

The FDA Mammography Web Site provides a listing of all FDA certified facilities by Zip Code or by selected State (or U.S. territory).

Cancer Information Service

Consumers and health professionals can also locate certified facilities in their geographic area by calling the National Cancer Institute's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237). Information specialists at this number have been trained to answer questions about mammography and breast cancer. Written documentation on mammography and breast cancer is also available on request.

National Technical Information Service

The list of certified facilities is also available on a computer diskette and sold as either a single issue (the most recent diskette) or a subscription (the diskette is updated quarterly).

National Technical Information Service (NTIS)
5285 Port Royal Road
Springfield, VA 22161

To order a single disk, call 1-800-363-2068. The NTIS order number is SUB-5386/Code D01.